

EXHIBIT E



SURESTEP™ Foley Tray System

Foley Catheter Insertion & Removal Sample Procedure

Purpose: To increase clinical knowledge of the SURESTEP™ Foley Tray System. This sample procedure is not intended as a replacement for the IFU. The end user bears the responsibility for including their own procedure and protocol in practice.

Supplies: SURESTEP™ Foley Catheter Tray

Procedure: Foley Catheter Insertion

1. Confirm patient meets the CDC Guidelines for Appropriate Indications for Indwelling Urethral Catheter Use:
 - a. Patient has acute urinary retention or bladder outlet obstruction
 - b. Need for accurate urine output measurements
 - c. Use for selected surgical procedures
 - d. To assist in healing of open sacral or perineal wounds
 - e. Patient requires prolonged immobilization
 - f. To improve comfort for end of life care
2. Select the smallest Foley catheter possible, consistent with good drainage
3. Insert Foley Catheter using aseptic technique and sterile equipment
 - a. Wash hands and don clean gloves
 - b. Position the patient
 - c. Open outer packaging of the Foley catheter tray and place it between the patient's legs
 - d. Remove the label, directions for use brochure, and orange sticker sheet and set aside
 - e. Open Peri-care kit
 - f. Use the provided packet of castile soap wipes to cleanse patient's peri-urethral area
 - g. Discard gloves and perform hand hygiene with provided alcohol hand sanitizer gel
 - h. Remove band from around Foley tray
 - i. Using proper aseptic technique open CSR wrap
 - j. Don sterile gloves provided
 - k. Place underpad beneath patient, plastic or "shiny" side down. Take caution not to contaminate sterile gloves



- l. Position fenestrated drape on patient appropriately
 - m. Open Povidone iodine packet and pour solution onto 3 foam swab sticks to saturate them
 - n. Attach the water-filled syringe to the inflation port (Note: It is not necessary to pre-test the Foley catheter balloon)
 - o. Use the syringe with the green plunger to deposit lubricant into tray
 - p. Remove Foley catheter from wrap and place catheter in lubricant
 - q. Prepare patient with povidone-iodine saturated foam swab sticks. Gently twist the swabs to remove them from the tray (Note: Use each swab stick for one swipe only)
 - i. Female Patient: With a downward stroke cleanse the labia minora furthest from you and discard the swab. Repeat for labia minora closest to you. Use the last swab to cleanse the area between the labia minora
 - ii. Male Patient: Cleanse the penis in a circulate motion starting at the urethral meatus and working outward
 - r. Proceed with catheterization until urine is visible in the drainage tube, insert catheter two more inches for females and to the bifurcation for males (or per hospital protocol), and inflate catheter balloon using entire 10mL of sterile water provided in the prefilled syringe (Note: Use of less than 10mL can result in asymmetrically inflated balloon)
 - s. Once inflated, gently pull catheter until the inflated balloon is snug against the bladder neck
 - t. Discard all materials in accordance with hospital protocol and remove contaminated gloves
 - u. Perform hand hygiene
4. If provided, secure the Foley catheter to the patient using the StatLock® Foley Stabilization Device (Note: Please make sure patient is appropriate for use of StatLock® device)
 5. Position hanger on bed rail at the foot of the bed so bag is hanging below the level of the bladder and use green sheeting clip to secure drainage tube to sheet, confirm tube is not kinked
 6. Indicate time and date of catheter insertion on provided labels and place designated labels on patient chart and drainage system
 7. Document procedure according to hospital protocol
 8. Provide patient/family member Foley catheter education to encourage them to take active role in preventing catheter-associated urinary tract infections, document education according to hospital protocol
 9. Maintain red tamper evident seal per hospital protocol
 10. Assess need for catheter routinely



Procedure: Foley Catheter Removal

1. Explain the procedure to the patient and ensure privacy
2. Perform hand hygiene
3. Don clean gloves
4. Remove STATLOCK® Foley stabilization device
5. Position patient and place a waterproof pad under patient
6. To deflate catheter balloon: Back off luer lock or slip tip syringe to 0.5mL and insert into the inflation port. Allow the pressure within the balloon to force the plunger back and fill the syringe with water (if slow or no deflation is noticed, re-seat the syringe gently)
7. Use only gentle aspiration to encourage deflation if needed as vigorous aspiration may collapse the inflation lumen, preventing balloon deflation
8. If the balloon will not deflate and if permitted by hospital protocol, the valve arm may be severed. If this fails, contact adequately trained professional for assistance, as directed by hospital protocol
9. Should balloon rupture occur, care should be taken to assure that all balloon fragments have been removed from the patient
10. Remove the catheter, discard it and document procedure according to hospital protocol

Foley catheters are intended for use in the drainage and/or collection and/or measurement of urine.

Cautions: Latex Foley catheters contain natural rubber latex which may cause allergic reactions. Federal (U.S.A.) law restricts these devices to sale by or on the order of a physician.

Warnings: On catheter, do not use ointments or lubricants having a petrolatum base. They will damage the catheter and may cause balloon to burst.

Do not use if allergic to iodine.

After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practices and applicable local, state and federal laws and regulations.

Visually inspect the product for any imperfections or surface deterioration prior to use. If package is opened or if any imperfection or surface deterioration is observed, do not use.

Please consult product label and insert for any indications, contraindications, hazards, warnings, cautions and directions for use.